DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 20, 2015

Finapres Medical Systems
c/o Ms. Iris van Uitert
Quality Manager
Hogehilweg 8
NL - 1101 CC Amsterdam
The Netherlands

Re: K141460
Trade/Device Name: Finapres Nova
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II
Product Code: DXN, DSB, DQA, DRT
Dated: February 2, 2015
Received: February 5, 2015

Dear Ms. Van Uitert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance. You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K141460

Device Name
Finapres NOVA

Indications for Use *(Describe)*

The Finapres NOVA is intended to be used with patients who have a need for a noninvasive blood pressure and hemodynamic monitor. The noninvasive blood pressure waveform is measured on the subject's finger. The Finapres NOVA provides a noninvasive characterization of the arterial circulation and its beat-to-beat variability in pressure and flow and in various hemodynamic parameters derived from these pressure and flow signals. Cardiac output derived from the flow signal requires a calibration with thermal dilution.

The Finapres NOVA has the option to include additional modules to extend its functionality with ECG and SpO2 measurements and blood pressure calibration.

When the SpO2 module is present, the Finapres NOVA can additionally monitor the functional oxygen saturation of arterial hemoglobin (SpO2) and the pulse rate.

When the ECG module is present, the Finapres NOVA can additionally monitor the ECG parameters of a patient and their pulse rate. Alarms concerning the pulse rate will be available from the monitor.

When the blood pressure calibration module is present, the Finapres NOVA can additionally provide an upper arm non-invasive blood pressure measurement to determine the blood pressure value for calibration.

The Finapres NOVA is intended to be used for subjects above 18 years of age.

The Finapres NOVA is intended for use in a professional medical environment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Food and Drug Administration
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Finapres NOVA - K141460

This 510(k) summary is being submitted in accordance with the requirements of SMDA and 21CFR § 807.92.

1. Submitter's information

Submitter: Finapres Medical Systems B.V.
Hogehilweg 8
NL-1101 CC Amsterdam
The Netherlands
Phone number: +31 20 609 0974
Fax Number: +31 20 609 0677
Operator Number: 9051428
Registration number: 3003803088

Contact person: Dr. Ir. Iris van Uitert
Quality Manager
Phone number: +31 20 609 0974
E-mail:iris.van.uitert@finapres.com

Date of preparation: March 17, 2015

2. Device information

Trade name:	Finapres NOVA Noninvasive Hemodynamic Monitor
Common name(s)	Noninvasive Blood Pressure Monitor
	Hemodynamic Monitor
	Electrocardiograph
	Oximeter
Classification name	See Table 1
Device classification	Class II

Table 1. Classification name

Classification name	21 CFR Section	Product Code
Noninvasive Blood Pressure Monitor Measurement System	870.1130	DXN
Plethysmograph, Impedance	870.2770	DSB
Oximeter	870.2700	DQA
Cardiac monitor	870.2300	DRT

3. Predicate Devices

The Finapres NOVA is substantially equivalent in design (methodology) and indications for use to the devices shown in Table 2 that have previously been cleared:

Table 2. Predicate devices for the Finapres NOVA

Device name	Manufacturer	510(k)
Finometer® Model-1	FMS, Finapres Medical Systems, Amsterdam, The Netherlands	K023723
Ohmeda 2350 Finapres ® Blood pressure monitor	Ohmeda Medical, Englewood	K880572
Portapres	FMS, Finapres Medical Systems, Amsterdam, The Netherlands	K023338
NEXFIN_HD™	BMEYE B.V., Amsterdam, The Netherlands	K072049
Nellcor Oximax N-600X Pulse Oximeter	Nellcor Puriton Bennet, Inc, Pleasanton	K060576
Zoll M Series with real CPR help	Zoll Medical Corporation, 269 Mill Road, Chelmsford	K062537
MOVES	THORNHILL RESEARCH INC, Toronto, Ontario	K093261

4. Description

The Finapres NOVA is an instrument to noninvasively monitor blood pressure and hemodynamic parameters. The Finapres NOVA provides a characterization of the arterial circulation and its beat-to-beat variability in pressure and flow and in various hemodynamic parameters derived from these pressure and flow signals. The Finapres NOVA has the option to include four additional modules to extend its functionality with ECG and SpO_2 measurements, blood pressure calibration and data transfer to and from the device.

The embedded software in the device provides computation of real-time and beat-to-beat blood pressure as well as hemodynamic parameters from the non-invasely measured blood pressure waveform. Hemodynamic parameters include cardiac output based on the modelflow method and total peripheral resistance.

The measurement of blood pressure in a finger is based on the arterial volume-clamp method of the Czech physiologist J. Peñáz, and the Physiocal - physiological calibration - criteria for the proper unloading of the finger arteries of K.H. Wesseling. With this method, finger arterial pressure is measured using a finger cuff and an inflatable bladder in combination with an infrared plethysmograph, which consists of an infrared light source and detector.

The SpO2, upper arm calibration and ECG modules used in the Finapres NOVA are commercially available OEM modules that are used in FDA approved systems. The finger blood pressure measurement module used in the system is similar to other Finapres Medical Systems B.V. devices available on the market. The analog input/output module has been developed by Finapres during the Finapres NOVA development.

5. Indications for use

The Finapres NOVA is intended to be used with patients who have a need for a noninvasive blood pressure and hemodynamic monitor. The noninvasive blood pressure waveform is measured on the subject's finger. The Finapres NOVA provides a noninvasive characterization of the arterial circulation and its beat-to-beat variability in

pressure and flow and in various hemodynamic parameters derived from these pressure and flow signals. Cardiac output derived from the flow signal requires a calibration with thermal dilution.

The Finapres NOVA has the option to include additional modules to extend its functionality with ECG and SpO2 measurements and blood pressure calibration.

When the SpO2 module is present, the Finapres NOVA can additionally monitor the functional oxygen saturation of arterial hemoglobin (SpO2) and the pulse rate.

When the ECG module is present, the Finapres NOVA can additionally monitor the ECG parameters of a patient and their pulse rate. Alarms concerning the pulse rate will be available from the monitor.

When the blood pressure calibration module is present, the Finapres NOVA can additionally provide an upper arm non-invasive blood pressure measurement to determine the blood pressure value for calibration.

The Finapres NOVA is intended to be used for subjects above 18 years of age.

The Finapres NOVA is intended for use in a professional medical environment.

6. Intended Use

The Finapres NOVA is intended to be used with patients with a need for a noninvasive blood pressure and hemodynamic monitor. The noninvasive blood pressure waveform is measured on the subject's finger. The Finapres NOVA provides a noninvasive characterization of the arterial circulation and its beat-to-beat variability in pressure and flow and in various hemodynamic parameters derived from these pressure and flow signals.
The Finapres NOVA has the option to include four additional modules to extend its functionality with ECG and SpO_2 measurements, blood pressure calibration and data transfer to and from the device.

The Finapres NOVA is used in a professional medical environment such as hospitals, clinics and research institutions. The Finapres NOVA is a standalone device intended for desktop use. Measurements are to be performed under uninterrupted patient surveillance of the operator.

The user of the Finapres NOVA should be a qualified operator. The operator should have knowledge of the system and data interpretation, obtained via medical education, system manuals and/or specific courses. The device does not report any diagnosis but provides numerical values. It is the physician's responsibility to make proper judgments based on these numbers.

7. Summary of Technical Comparison with predicate devices

The Finapres NOVA is an updated model of the Ohmeda 2350, the Portapres and the Finometer® Model-1 device. As with predicate devices, the Finapres NOVA is indicated for use as a noninvasive blood pressure monitor. The Finapres NOVA is used to provide real-time and on-line monitoring and trending of hemodynamic parameters just as with the Finometer® Model-1 devices.

The Ohmeda 2350 device and the Finometer® Model-1 device have the same indications for use, the same design, and the same methodology as the Finapres NOVA Noninvasive

Hemodynamic Blood Pressure Monitor. The predicate Ohmeda 2350, the Finometer® Model-1 and the Nexfin_HD provide the same noninvasive measurement and display of finger arterial blood pressure and pulse rate monitoring as the Finapres NOVA.

The Finapres NOVA consists of the same device architecture as the Finometer® Model-1 and the Nexfin_HD.

The Finapres NOVA uses functionally the same embedded software for controlling the measurements as that used in the Finometer® Model-1 and Portapres device. The Finapres NOVA uses the proprietary NOVAScope/Modelflow software program for the measurement and trending of hemodynamic parameters, which is an updated version of the software that was used for data analysis in the Finometer and for the Portapres.

The Finapres NOVA can be equipped, equivalent to the Finometer® Model-1 and Nexfin_HD, with a blood pressure calibration method and does, therefore, allow for the measurement of accurate absolute blood pressure data complying with the AAMI SP10 :2002 and its successor IEC 81060-2:2009. The Finapres NOVA has, similar to the Nexfin_HD and the Finometer® Model-1, an optional Height correction unit (HCU) that allows the patient free hand movement during measurements with the device. The Finapres NOVA has, similar to the Finometer® Model-1, an optional ECG module that provides an analog ECG which is sampled and stored simultaneously with the blood pressure waveform. The Finapres NOVA has, same as the Ohmeda 2350, an optional SpO2 module that provides an SpO2 signal which is sampled and stored simultaneously with the blood pressure waveform. Similar to the Portapres, the Finapres NOVA enables 24 continuous measurements.

The three optional modules are available in the following predicate devices: MOVES, K093261; Nellcor Oximax N-600X Pulse Oximeter, K060576; Zoll M Series with real CPR help, K062537.

8. Non-clinical performance data for substantial equivalence determination

Testing of the Finapres NOVA was performed according to medical device safety standards shown in Table 3.

Table 3.Medical device standards that the Finapres NOVA is tested against

Standard number	Standard name
ANSI/AAMI ES60601-1:2005 / A2:2010	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1:1988 +A1:1991 + A2:1995 (2nd edition)	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2007	Medical electrical equipment – Part 1-2: General requirements for safety –Electromagnetic compatibility – Requirements and tests
IEC 60601-1-4 1996 + Am.1 1999	Medical electrical equipment - Part 1-4 - Collateral Standard: Programmable electrical medical systems
IEC 60601-1-8: 2006	Medical electrical equipment -- Part 1-8: General requirements for basic safety and essential performance -- Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-1-8: 2003 + A1:	Medical electrical equipment -Part 1-8: General requirements

2006	for safety – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-2-27:2005	Medical electrical equipment – Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment
IEC 80601-2-30:2009	Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
ISO 9919:2005	Medical electrical equipment – Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
ISO 80601-2-61:2011	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.
ISO 81060-2:2009	Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type
ISO 14971:2007	Medical devices – Risk management – Application of risk management to medical devices
IEC 62304:2006	Medical device software – software life cycle processes
IEC 62366:2009	Medical devices – Application of usability engineering to medical devices.
ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing
AAMI / ANSI / ISO 10993-5:2009	Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Software performance was established according to FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, consistent with moderate level of concern.

The data provided demonstrates that the Finapres NOVA met all applicable requirements and that it is substantially equivalent to its predecessors Finometer® Model-1 and Ohmeda 2350 and to the Nexfin_HD™.

9. Clinical performance data for substantial equivalence determination

Clinical performance data was not required to demonstrate substantial equivalence.

10. Conclusion

On basis of the information above, it is concluded that the device is as safe, as effective, and performs as well as, or better than, the predicate devices.

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9. Clinical performance data for substantial equivalence determination

Clinical performance data was not required to demonstrate substantial equivalence.

10. Conclusion

On basis of the information above, it is concluded that the device is as safe, as effective, and performs as well as, or better than, the predicate devices.